

## **REMARKS**

### **Amendments**

Claims 80, 97-114 and 157-158 are canceled. Claims 81-96, 115-127 and 159 are pending.

In the interest of expediting the prosecution of this Application, Applicant cancels Claim 80, 97-114 and 157-158, and amends Claims 81-82, 94, 118 and 159. Applicant reserves the right to reintroduce the original claims in one or more continuation type of application.

Claims 81-82, 94 and 115 are amended to depend from Claim 159.

Claims 84-85 are amended to replace "active agent" with "ubiquinone or DHEA". Support for this amendment is found, for example, in Claims 84-85 as originally filed.

Claim 96 is amended to delete the term "other therapeutic agents". Support for this amendment is found, for example, in Claim 96 as originally filed.

Claim 115 is amended to delete the phrase "which may further comprise an ingredient selected from folic acid, other therapeutic agents, preservatives, antioxidants, flavoring agents, volatile agents, buffering agents, dispersants or surfactants". Support for this amendment is found, for example, in Claim 115 as originally filed.

Claims 116-199 are amended to replace "active agent" with "formulation". Support for this amendment is found, for example, in Claims 116-119 as originally filed.

Claim 118 is amended to delete the term "nasal". Support for this amendment is found, for example, in Claim 118 as originally filed.

Claim 159 is amended to convert it into an independent claim by adding the limitations of Claim 80. Support for this amendment is found, for example, in Claims 80 as originally filed.

Claim 159 is amended to recite "said pharmaceutical composition is an inhalable, respirable, or intrapulmonary formulation". Support for this amendment is supported is found, for example, in Claim 114 as originally filed.

Applicant respectfully contends that the amendments will place the case in condition for allowance. No new matter is added in any of the above amendments and the Examiner is respectfully requested to enter the amendments and reconsider the application.

## **Response**

### **1. 35 U.S.C. 112, second paragraph.**

The Examiner rejects Claims 106 and 120-127 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the Office Action, the Examiner states that "Claims 98-107 and 120-127 are rejected under 35 U.S.C. 112, second paragraph as being indefinite". In the same Office Action the Examiner has also stated that the rejection of Claims 98-107 and 111-119 is removed with respect to the term "the formulation". Therefore Applicant assumes that the inclusion of Claims 98-105, and 107 in this rejection is a typographical mistake.

The Examiner rejects Claim 106 for the expression "other therapeutic agent" in that allegedly the expression "other therapeutic agent" renders Claim 106 indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Claim 106 is canceled. Therefore the Examiner should withdraw this basis of rejection.

The Examiner rejects Claims 120-127 for the limitation "the kit" in that allegedly there is insufficient antecedent basis for this limitation. Applicant traverses this rejection in that Claim 120 does not recite the term "kit". Also, Applicant traverses this rejection in that Claim 121 recites "A kit", and thereby provides sufficient antecedent basis for "the kit" in Claims 122-127. Therefore the Examiner should withdraw this basis of rejection.

### **2. 35 U.S.C. § 102**

**The Examiner's rejection of Claims 80-85, 94-100, 103-106 and 108 under 35 U.S.C. § 102(b) over Langsjoen et al. (U.S. 5,011,858) should be withdrawn, because Langsjoen et al. do not disclose the use of DHEA.**

The Examiner rejects Claims 80-85, 94-100, 103-106 and 108 under 35 U.S.C. § 102(b) as being unpatentable over Langsjoen et al. (U.S. 5,011,858).

Claims 80, 97-100, 103-106 and 108 are canceled. Claims 81-85 and 94-96 are amended to depend from Claim 159. Claim 159 is directed to a pharmaceutical composition comprising a

ubiquinone and DHEA. Langsjoen et al. do not anticipate Claims 81-85 and 94-96 because Langsjoen et al. do not disclose DHEA. Therefore Langsjoen et al. do not anticipate Claims 81-85 and 94-96, and the Examiner should withdraw this rejection.

**The Examiner's rejection of Claims 80-85, 94-103, 107-108 and 113 under 35 U.S.C. § 102(b) over Brasey et al. (U.S. 4,778,798) should be withdrawn, because Brasey et al. do not disclose the use of DHEA.**

The Examiner rejects Claims 80-85, 94-103, 107-108 and 113 under 35 U.S.C. § 102(b) as being unpatentable over Brasey et al. (U.S. 4,778,798).

Claims 80, 97-103, 107-108 and 113 are canceled. Claims 81-85 and 94-96 are amended to depend from Claim 159. Claim 159 is directed to a pharmaceutical composition comprising an ubiquinone and DHEA. Brasey et al. do not anticipate Claims 81-85 and 94-96 and 113 because Langsjoen et al. do not disclose DHEA. Therefore Brasey et al. do not anticipate Claims 81-85 and 94-96, and the Examiner should withdraw this rejection.

**The Examiner's rejection of Claims 80-85, 94-99 and 111 under 35 U.S.C. § 102(b) over Bertelli et al. (U.S. 4,654,373) should be withdrawn, because Bertelli et al. do not disclose the use of DHEA.**

The Examiner rejects Claims 80-85, 94-99 and 111 under 35 U.S.C. § 102(b) as being unpatentable over Bertelli et al. (U.S. 4,654,373).

Claims 80, 97-99 and 111 are canceled. Claims 81-85 and 94-96 are amended to depend from Claim 159. Claim 159 is directed to a pharmaceutical composition comprising an ubiquinone and DHEA. Bertelli et al. do not anticipate Claims 81-85 and 94-96 because Langsjoen et al. do not disclose DHEA. Therefore Bertelli et al. do not anticipate Claims 81-85 and 94-96, and the Examiner should withdraw this rejection.

### 3. 35 U.S.C. § 103(a)

**The Examiner's rejection of Claims 109-110, 112, and 114-127 under 35 U.S.C. § 103(a) over Langsjoen et al., Brasey et al., and Bertelli et al. in view of Lieberman et al. should be withdrawn, because these references do not disclose the use of DHEA.**

The Examiner rejects Claims 109-110, 112, and 114-127 under 35 U.S.C. § 103(a) as being unpatentable over Langsjoen et al., Brasey et al., and Bertelli et al. in view of Lieberman et al.

Claims 109-110, 112, and 114 are canceled. Langsjoen et al., Brasey et al., and Bertelli et al. in view of Lieberman et al. do not render Claims 115-127 obvious. Claims 115-127 depend from Claim 159 which is directed to a pharmaceutical composition comprising a ubiquinone and DHEA. As explained earlier, Langsjoen et al., Brasey et al., and Bertelli et al. do not disclose the use of DHEA. This deficiency of Langsjoen et al., Brasey et al., and Bertelli et al. is not overcome by the disclosure of Lieberman et al. Lieberman et al. also do not disclose the use of DHEA. One of ordinary skill in the art, relying on Langsjoen et al., Brasey et al., Bertelli et al., and Lieberman et al. would not be led to the formulation of Claims 115-127, comprising a ubiquinone and DHEA.

Therefore Langsjoen et al., Brasey et al., and Bertelli et al. in view of Lieberman et al. do not render Claims 115-127 obvious. The Examiner should with this rejection.

#### 4. 35 U.S.C. § 102

**The Examiner's rejection of Claims 80, 86-93, and 159 under 35 U.S.C. § 102(b) as being anticipated by Nyce (U.S. 5,527,789) should be withdrawn, because Nyce does not disclose a pharmaceutical composition which is an inhalable, respirable, or intrapulmonary formulation.**

The Examiner rejects Claims 80, 86-93 and 159 under 35 U.S.C. § 102(b) as being anticipated by Nyce (U.S. 5,527,789).

Claim 80 is canceled. Claims 86-93 are amended to depend from Claim 159. Claim 159 is directed to a pharmaceutical composition comprising an ubiquinone and DHEA wherein said pharmaceutical composition is an inhalable, respirable, or intrapulmonary formulation.

Nyce discloses an anticancer formulation comprising ubiquinone and DHEA. However Nyce does not disclose the formulation to be an inhalable, respirable, or intrapulmonary formulation. Therefore Nyce does not anticipate Claims 86-93 and 159. The Examiner should with this rejection.

## 5. Double Patenting

The Examiner's rejection of Claims 80, 86-93 and 159 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 13-19 of U. S. Patent No. 5,527,789 should be withdrawn, because the use of ubiquinone and DHEA to combat heart cancer does not render obvious an inhalable, respirable, or intrapulmonary formulation of ubiquinone and DHEA to alter levels of, or sensitivity to, adenosine in a subject's tissue, or treat bronchoconstriction, lung inflammation or allergy(ies), or chronic obstructive pulmonary disease.

The Examiner rejects Claims 80, 86-93 and 159 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 13-19 of U.S. Patent No. 5,527,789 (hereafter "the '789 patent"). Applicant traverses this rejection.

Claim 80 is canceled. Claims 86-93 and 159 are not obvious over Claims 13-19 of the '789 patent. Claims 86-93 and 159 are directed to a pharmaceutical composition comprising a ubiquinone and DHEA, in amounts effective for altering levels of, or sensitivity to, adenosine in a subject's tissue, or treating bronchoconstriction, lung inflammation or allergy(ies), chronic obstructive pulmonary disease or a disease associated with either of them, wherein the pharmaceutical composition is inhalable, respirable, or intrapulmonary formulation. Claims 13-19, of the '789 patent, are directed to a pharmaceutical formulation comprising DHEA or an analog thereof in an amount effective to combat cancer and a ubiquinone in an amount effective to combat heart failure induced by said DHEA or analog thereof in a pharmaceutically acceptable carrier. A pharmaceutical formulation comprising DHEA in an amount effective to combat cancer and ubiquinone in an amount effective to combat heart failure induced by said DHEA does not render obvious a pharmaceutical composition comprising a ubiquinone in an amount effective for altering levels of, or sensitivity to, adenosine in a subject's tissue, or treating bronchoconstriction, lung inflammation or allergy(ies), chronic obstructive pulmonary disease that is an **inhalable, respirable, or intrapulmonary formulation**. This is because the disclosure of a formulation to combat cancer does not teach or suggest an **inhalable, respirable, or intrapulmonary formulation**. Further, (1) the disclosure that ubiquinone can combat heart failure (induced by administered DHEA) does not disclose or suggest that ubiquinone can be

used for altering levels of, or sensitivity to, adenosine in a subject's tissue, or treating bronchoconstriction, lung inflammation or allergy(ies), chronic obstructive pulmonary disease, and (2) the disclosure of the amount of ubiquinone effective to combat heart failure does not disclose or suggest the amount of ubiquinone effective to alter levels of, or sensitivity to, adenosine in a subject's tissue, or treat bronchoconstriction, lung inflammation or allergy(ies), chronic obstructive pulmonary disease.

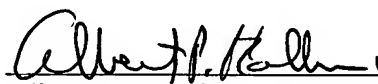
Therefore Claims 86-93 and 159 are not unpatentable under the judicially created doctrine of obviousness-type double patenting over Claims 13-19 of the '789 patent. The Examiner should with this rejection.

### CONCLUSION

In view of the foregoing amendment and remarks, the Applicant believes that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 463-8109.

Respectfully submitted,

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